IMPLEMENTATION OF ADVANCED THERAPY MEDICINAL PRODUCTS (ATMP) RECONSTITUTION IN A UNIVERSITY TEACHING HOSPITAL IN FRANCE: PROPOSAL OF A DECISION-MAKING ALGORITHM

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Background and Importance
ATMP (genetically modified organisms (GMO) ones or not), use is rising in oncology, requires establishment of a specific organization to ensure a safety circuit.

Aim and objectives
To implement ATMPs reconstitution in our institution, we built a decisional algorithm for risk and feasibility assessment for each ATMPs.

Material and methods

7 oncology pharmacists

Several competencies

3 brainstorming sessions

Regulation & Professional guidelines & Organization of our institution

Criticals points were retained

A decision-making algorithm based on a yes/no dichotomy progression was built

Validated with circuit of ATMPs in clinical trials (CT) ever conducted

Results

6 steps

○ ATMP Nature
○ Storage conditions
○ Thawing conditions
○ Preparation of a not-GMO ATMP
○ Preparation of a GMO-ATMP
○ Waste disposal

34 questions

If a step fails, ATMP can’t be used

Conclusion and relevance

This tool was used prospectively to implement tisagenlecleucel, onasemnogene abeparvovec and soon betibéglogene autotemcel in our center. Furthermore, French Regional Health Agency identified it as a key point to secure our ATMPs circuit.

Retrospective scrutiny of our algorithm with ATMPs circuits ever conducted in clinical trials:
• talimogene laherparepvec
• axicabtagene ciloleucel

It appeared to meet all our needs